K132832

Section 5

FEB 13 2014

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 09-05-2013 [21 CFR 807.92(a)(1)].

A. Applicant Name and Address [21 CFR 807.92(a)(1)]

ActivaTek Inc.

2734 S. 3600 West

Unit F

West Valley, UT 84119

Tel: (800) 680-5520

Fax: (800) 680-5520

B. Contact Information

ActivaTek Inc.

2734 S. 3600 West

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West Valley, UT 84120

Tel: (800)-680-5520

Fax: (800) 680-5520

Contact person: Jamal Yanaki, President & CEO

jyanaki@activatekinc.com

C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *ActivaPatch ET* Iontophoresis Patch
Device Common Name: Iontophoresis Patch Electrode
Classification Name: Iontophoresis, other uses 21 CFR 890.5525
Product Code: EGJ
Device Classification: Class III

D. Predicate Devices [21 CFR 807.92(a)(3)]

The *ActivaPatch ET* Iontophoresis Patch uses similar technology and physical output fied characteristics as the following predicate devices:
K030395 EMPI Action Patch
K061522 Activatek *Trivarion* Iontophoresis Electrode
K033192 Iomed *RH-950* Iontophoresis Patch

E. Device Description [21 CFR 807.92(a)(4)]

The Activatek *ActivaPatch ET* Iontophoresis Patch consists of a self-contained, disposable single-use iontophoresis patch, instructions for use, and an alcohol prep pad containing 70% isopropyl alcohol.

The *ActivaPatch ET Iontophoresis Patch* contains an electronic module, an Active Electrode, and a Return Electrode. These elements are incorporated under an adhesive non-woven fabric covering which adheres the device to the skin. The overall dimensions of the *ActivaPatch ET* are 5.7 inches (length), 3.4 inches (width), and 0.2 inches (thickness).

Principle of Operation: Iontophoresis is a process that uses an electrical field across intact skin to propel charged ions into the skin and underlying tissue. The electrodes (Active and Return) are applied directly to the skin to transit the electric field. If the ion is negatively charged, then the negative electrode is designated the Active Electrode and the positive electrode is the Return Electrode. The total dose of all ions transported through the skin is proportional to the total current passed between the electrodes. Units of iontophoresis dosages are conventionally given in terms of mAmp*min, calculated by multiplying the amount of current by the time of application of the current.

F. Device Specifications and Comparison to Predicates [21 CFR 807.92(a)(6)]

The *ActivaPatch ET* Intophoresis Patch delivers a calibrated dose of 80 mAmp*min. It operates with a voltage of 3V. Both the Action Patch (K030398) and the RH-950 (K033192) deliver identical dosages of 80 mAmp*min. The operating voltage of the *ActivaPatch ET* is intermediate between the *Action Patch* at 10.5 Volts and the *RH-950* at 1.55 Volts. The *ActivaPatch ET* delivers the calibrated dosage of 80 mAmp*min by way of a calibrated shunt resistor, similar to the Action Patch (K030395). The indications for use and intended use are similar to the EMPI *Action Patch* and the Iomed *RH-950* (K033192). Both patches are to be placed in clinic, worn home, and removed by patient.

The materials used for patient contacting parts evolved from the ActivaTek *Trivarion* Iontophoresis Electrodes (K061522). The *ActivaPatch ET* has Active and Return Electrodes that are made of identical materials as used in the *Trivarion* Iontophoreisis Electrodes. The adhesive backing is similar between the *ActivaPatch ET* and the *Trivarion* systems.

G. Indications for Use [21 CFR 807.92(a)(5)]

The Activatek *ActivaPatch ET* Intophoresis Patch is intended to be used for the administration of soluble salts into the body for medical purposes and as an alternative to hypodermic injection.

H. Performance Data [21 CFR 807.92(b)(2)]

There are no applicable Guidance Documents specifically associated with this type of medical device.

I. Conclusion [21 CFR 807.92(b)(3)]

The ActivaTek *ActivaPatch ET* Iontophoresis Patch was found to be substantially equivalent to the predicate devices in terms of technology, function and intended use. The indications for use are identical to the previously cleared devices (K033192) Iomed *RH-950* Iontophoresis Patch. The dosage circuitry is similar to the EMPI *Action Patch* (K030395). The electrode composition is similar to the Activatek *Trivarion Electrode* (K061522). The ActivaTek *ActivaPatch ET* is substantially equivalent in intended use, materials of construction, mode of operation, and performance characteristics. We believe that there are no new questions of safety or efficacy raised by the introduction of the ActivaTek *ActivaPatch ET* Iontophoresis System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2014

ActivaTek Inc.
Jamal Yanaki, President & CEO
2734 S. 3600 West, Unit F
West Valley City, UT 84119

Re: K132832
Trade/Device Name: ActivaPatch ET Iontophoresis Patch
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: January 7, 2014
Received: January 8, 2014

Dear Mr. Yanaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), that do not require approval of a premarket approval application (PMA), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the device as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132832

Device Name
Activatek ActivaPatch ET Iontophoresis Patch

Indications for Use *(Describe)*
The Activatek ActivaPatch ET Iontophoresis Patch is intended to be used for the administration of soluble salts into the body for medical purposes and as an alternative to hypodermic injection.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PRAStaff@fda.hhs.gov

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